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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,517	01/03/2002	Xuanchuan Sean Yu	LEX-0293-USA	6008

7590 02/06/2004

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EXAMINER	
NASHED, NASHAAT T	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 02/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/038,517	YU ET AL.	
	Examiner	Art Unit	
	Nashaat T. Nashed	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *03 January 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/19/02 & 12/10/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-4 are pending and under consideration.

The abstract of the disclosure is objected to because it does not describe the claimed invention. Correction is required. See MPEP ' 608.01(b).

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

Applicants disclose the nucleic acid of SEQ ID NO: 1 which encodes the polypeptide of SEQ ID NO: 2. Based on a reasonable sequence homology with a known lipase, the polypeptide of SEQ ID NO: 2 is sought to be a lipase, which is a non-specific asserted utility. Lipase is a class of enzymes, which catalyze the hydrolysis of many lipids having different structure and functions. Thus, each lipase is expected to have a specific substrate(s) and function. The specification does not specifically disclose a specific function of the polypeptide of SEQ ID NO: 2, its relationship to any disease, or any specific real world use. The specification describes non-specific functions for the protein, nucleic acid, and antibodies. The utility of the nucleic acid is said to be used in a method to detect a human gene and to recombinantly make the polypeptide of SEQ ID NO: 2 which neither the gene or the polypeptide associated with a specific use or a disease. The mere fact that the polypeptide disclosed in the specification named novel human lipase (NHL) is indicative that the applicants have no idea about the specific function of this polypeptide at the time they filed their application. It appears that the main utility of the polypeptide and nucleic acid is to carry out further research to identify the biological function and possible diseases associated with said function. Substantial utility defines a real world use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a real world context of use are not substantial utility. Thus, the claimed invention has no specific or substantial asserted utility.

Applicant is referred to the revised interim guidelines concerning compliance with utility requirement of 35 U.S.C. 101, published in the Official Gazette and also available at www.uspto.gov.
The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim 1-3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claim 1 and 2, they are directed to all possible nucleic acid sequences comprising 24 contagious nucleotide of SEQ ID NO: 1 isolated from any source and having any function, and that hybridizes to SEQ ID NO: 1 under any stringent conditions regardless of their function, respectively. The specification, however, only provides representative species of these nucleic acid sequences from human encoding a polypeptide that is asserted to be a lipase without identifying the actual function of the protein. Moreover, the specification fails to describe additional representative species of these nucleic acid sequences by any identifying structural characteristics or properties other than they encode polypeptides such as that of SEQ ID NO: 2. Since the specification lacks teaching of the function of the polypeptides and/or a structure function relationship, the specification fails to impart a high predictability of structure for any additional lipases. Given this lack of additional representative species as encompassed by the claim, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as the disclosure is not even enabling for claims limited to the nucleic or amino acid

sequences of SEQ ID NO: 1 and 2 from human. The specification does not enable any person skilled in the art to make and use the invention commensurate in scope with this claim. The claims are broader than the enablement provided by the disclosure with regard to all possible nucleic acid comprising 24 contagious nucleotide of SEQ ID NO: 1 or those that hybridize under any condition from any source to SEQ ID NO: 1. Factors to be considered in determining whether undue experimentation is required are summarized *In re* Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claimed invention encompasses any nucleic acid comprising 24 contagious nucleotide of SEQ ID NO: 1 or any nucleic acid that hybridizes to SEQ ID NO: 1 under any stringent conditions. Also, the claimed invention encompasses any nucleic acid encoding about any insertion, deletion, substitution and combination thereof mutants. The specification provides guidance and examples in the form of an assay to obtain the nucleic acid sequence of SEQ ID NO: 1 encoding the open reading frame of SEQ ID NO: 2. While molecular biological techniques and genetic manipulation to make any nucleic acid comprising 24 contagious nucleotide of SEQ ID NO:1 or that hybridizes under some stringent condition to SEQ ID NO: 1 are known in the prior art and the skill of the artisan are well developed, knowledge regarding their use, their biological source, the three dimension structure of the lipase of SEQ ID NO: 2, and methods of obtaining mutants of the polypeptide of SEQ ID NO: 2 having a desired activity or function is lacking. The amount of experimentation to identify a naturally occurring or a mutant polypeptide analog of SEQ ID NO: 2 having desired characteristic or having a specific or substantial utility is enormous. Since routine experimentation in the art does not include screening numbers genomic, cDNA, or man-made DNA where the expectation of obtaining the desired polypeptide is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the source of the DNA, a specific or a substantial utility for the nucleic acid or the polypeptide encoded thereby, a specific chemical assay method, and the three dimension structure of the polypeptide. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "stringent conditions" renders the claim indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Since there are several hybridization conditions known in the art as stringent conditions and the result of a hybridization experiment will vary with each set of stringent conditions, the claim is found indefinite. It is noted that the specification exemplifies a stringent hybridization conditions, see page 4, lines 30-34. Stating the hybridization conditions in the paragraph bridging pages 4 and 5 in the claim would overcome this rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Guegler *et al.* (US 2002/0052034 A1).

Guegler *et al.* teach a nucleic acid in Figure 1 encoding the polypeptide of SEQ ID NO: 3. Residues 9-1412 of the nucleic acid sequence in Figure 1 are identical to SEQ ID NO: 1 of the instant application. The amino acid sequence of SEQ ID NO: 3 is identical to SEQ ID NO: 2 of the instant application. Thus, the nucleic acid sequence taught Guegler *et al.* contains at least 24 contiguous

nucleotide of SEQ ID NO: 1 and is expected to hybridize under any stringent conditions to SEQ ID NO: 1 of the instant application (claims 1-3). Since the nucleic acid taught by Guegler *et al.* encodes SEQ ID NO: 2 of the instant application, it anticipates claims 2 and 4.

Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Khodadoust *et al.* [U. S. Patent 6,558,936 (936)].

The 936 patent teaches the human nucleic acid sequence of SEQ ID NO: 1 encoding the polypeptide SEQ ID NO: 2 which is described as lipase polypeptide, see the sequence listing. The 1404 nucleotide sequence of SEQ ID NO: 1 of the instant application has 1403 nucleotide identical to residues 125-1528 of SEQ ID NO: 1 of the 936 patent. Only one residue differs in both sequences. Also, the amino acid sequence of SEQ ID NO: 2 of the instant application differs only in one amino acid residue sequences from that of the 936 patent. Thus, the nucleic acid sequence taught in the 936 patent contains at least 24 contagious nucleotide of SEQ ID NO: 1 of the instant application and is expected to hybrdize to SEQ ID NO: 1 of the instant application under any stringent condition (claims 1-3).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached Monday, Tuesday, Thursday and Friday from 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph. D. can be reached on 571-272-0928. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nashaat T. Nashed, Ph. D.
Primary Examiner